

Purpose: To request IOAA approval to send ORD's Fall 2018 Regulatory Agenda submission to OP.

Background

- The Unified Agenda of Federal Regulatory and Deregulatory Actions, or Regulatory Agenda, is a semiannual compilation of information about regulations under development by federal agencies.
- Under Executive Order 12866, all agencies are required to publish their regulatory agendas, and EPA publishes its agenda as part of the Unified Agenda in both the spring and fall.
- OP is collecting EPA's entries for the Fall 2018 Regulatory Agenda. Entries are due to OP on July 13.
 - Regulatory Agenda entries include an external abstract and estimated dates for proposed and final rules.

ORD Regulatory Actions

- ORD has two regulatory actions that are responsive to this request:
 - "Harmonize 40 CFR Part 26 Subparts C, D and K with Subpart A (the Common Rule)" (SAN 5935, Tier 3)
 - ORD lead: Tom Sinks
 - "Strengthening Transparency in Regulatory Science" (SAN 6781, Tier 1)
 - ORD lead: Maria Doa
- To be responsive to OP's request, OSP:
 - Worked with the ORD leads for the actions to review and revise the estimated schedules and external abstracts for each action, and
 - Shared the revised external abstracts with OP and OGC for policy and legal review, respectively, and incorporated their comments.
- The draft final submissions for IOAA review are attached.

OSP Recommendation

- **Deliberative Process / Ex. 5**

Attachment: “Harmonize 40 CFR Part 26 Subparts C, D and K with Subpart A (the Common Rule)” (SAN 5935, Tier 3)Estimated Milestones

NPRM (notice of proposed rulemaking): September 2018

FRM (final rulemaking): January 2019

External Abstract

In 1991, several federal departments and agencies that conduct or support research involving human subjects adopted a common “Federal Policy for Protection of Human Subjects” into each of their own respective regulations. This policy is known as the “Common Rule,” by virtue of being shared currently by all these departments and agencies. The Common Rule was revised through the Federal rulemaking process and a final revised rule was jointly published in the Federal Register on January 19, 2017. Implementation of the Common Rule will occur on January 21, 2019.

The Common Rule was codified by EPA in 40 CFR 26. Beyond the Common Rule language, which is located in subpart A of part 26, 40 CFR 26 also contains several additional subparts that are unique to EPA, added in 2006 in response to a Congressional mandate. In particular, EPA created subparts K through Q to regulate third-party pesticide research. Subpart K borrowed heavily from the provisions of the Common Rule. In this rulemaking, EPA is updating subpart K for consistency with the recent updates to the Common Rule. Without appropriate updates, once the new Common Rule becomes effective, there will be a disconnect between policies and procedures in subpart K, which will be based on the previous version of the Common Rule, and the revised version of the Common Rule. In addition to the textual issues in subpart K, subparts C and D contain minor numerical citations (i.e., regulatory reference numbers) that are no longer accurate and should also be updated. Failure to resolve these internal discrepancies will create confusion and, more seriously, potential compliance and/or legal liabilities for researchers, institutions and sponsors who must follow EPA regulations. These updates are solely intended to resolve discrepancies created by the recent revision to the Common Rule, and will not alter the fundamental protections for human subjects, including vulnerable populations.

Attachment: “Strengthening Transparency in Regulatory Science” (SAN 6781, Tier 1)Estimated Milestones

FRM (final rulemaking): January 2020

External Abstract

This action is intended to strengthen the transparency of EPA regulatory science. As a result of this action, EPA would ensure that the data underlying the final significant regulations it promulgates are publicly available in a manner sufficient for independent validation. This action would increase transparency of the assumptions underlying dose-response data and models that support these EPA regulatory decisions. The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions.